510(k) SUMMARY

JUN 6 2013

SUBMITTER: Sorin Group Italia
86, Via Statale 12 Nord
41037 Mirandola (MO) Italy

CONTACT PERSON: Luigi Vecchi
Phone: 39 0535 29811
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DATE PREPARED: April 18, 2013

DEVICE TRADE NAMES: XRES Blood Collection Reservoir
XRES 120µm Blood Collection Reservoir

COMMON NAME: Blood Collection Reservoir

CLASSIFICATION NAME: Cardiopulmonary Bypass Blood Reservoir

UNMODIFIED DEVICE: XRES Blood Collection Reservoir (K100507)

DEVICE DESCRIPTION:

The XRES and XRES 120µm Blood Collection Reservoirs are modified versions of the currently marketed XRES reservoir. The XRES contains both a 40µm and a 120µm filtering material whereas the XRES 120µm only contains a 120µm filtering material.

The XRES and XRES 120µm reservoirs are sterile, non-pyrogenic device used to collect and filter blood salvaged during surgical procedures. Both reservoirs have an internal filtering system designed to filter and remove aggregates from the recovered blood.

During surgical procedures the devices operate by means of an external vacuum source to suction and filter blood from the operating field prior to subsequent processing by an autotransfusion device. Entrained air is removed from blood by the defoamer.

INDICATIONS FOR USE:

The XRES Blood Collection Reservoir is an accessory to an autotransfusion device and is intended for the sterile collection and filtration of recovered blood for subsequent processing for autotransfusion

The XRES 120µm Blood Collection Reservoir is an accessory to an autotransfusion device and is intended for the sterile collection and filtration of recovered blood for subsequent processing for autotransfusion

TECHNOLOGICAL CHARACTERISTICS:

The modified devices have the same principles of operation and control mechanisms as the unmodified devices.

The unmodified XRES contains two layers of filtering material; a 40µm non woven polyester filter covered by a 120µm polyester filter.
Due to customer preference, the device will be also offered without the 40µm polyester filter material. Devices without the 40µm will be referred to as the XRES 120µm.

The XRES 120µm will be provided with the 120µm polyester fabric only, which acts as a holder sock for the entire filter assembly. In order to accommodate the modified filtering system the shape of the blood conveyor has been changed and an o-ring has been placed at the bottom of the filtering assembly.
The XRES 120µm will be available with the BOTTOM configuration only (i.e. the reservoir outlet is on the bottom). The TOP configuration will not be available.

The modifications to the XRES consist of: the introduction of the same newly shaped blood conveyor for both BOTTOM and TOP configurations. The change is being implemented in order to provide consistency with the XRES 120µm product.

Also, the BOTTOM versions of modified XRES / XRES 120µm will be offered with and without a short piece of tube that ends in a 1/4" outlet port.
The short piece might be used as an alternative to the existing rigid ABS 1/4" outlet port. The outlet port size continues to be 1/4".

In addition, the 120µm polyester sock will be provided by a different supplier for the entire family of XRES devices. The raw material remains the same (polyester) and pore size is within the existing specification.

No change to the intended use has been made as a result of the modifications.

The modified and unmodified devices share the same fundamental technological characteristics except for some modifications that do not affect the basic device function.
These differences do not raise any new issues of safety and effectiveness.

The modified devices are substantially equivalent to the unmodified devices on the basis of operating principles and basic function.

There are no differences in packaging type and material between unmodified and modified device.

The modified devices are ethylene oxide sterilized and have a non-pyrogenic fluid path. The devices are for single use only.

NON CLINICAL TEST RESULTS:

Applicable tests were conducted in accordance with the requirements of ISO 10993-1 and the FDA May 1st, 1995 Memorandum on the use of the ISO 10993 standard for biocompatibility testing of materials.

IN VITRO TEST RESULTS:

In vitro testing was conducted in accordance with the relevant requirements of "Guidance for Extracorporeal Blood Circuit Defoamer 510(k) Submissions; Final Guidance for Industry and FDA" issued on November 29, 2000.
In vitro testing was conducted to demonstrate unmodified reservoir substantial equivalency and compliance to safety and effectiveness requirements. Since the XRES 120µm includes all the modifications introduced, the impact of the overall changes was evaluated by comparing XRES 120µm performances data to the XRES unmodified device.

The following table lists the performance and tests conducted to demonstrate compliance to the product's performance specifications. The XRES 120µm blood collection reservoir successfully met all acceptance criteria for each test.

TEST	TEST CLASSIFICATION	TEST TITLE
1	Functional/Performance	Break-through time and volume
2	Functional/Performance	Defoaming efficiency
3	Functional/Performance	Filtration efficiency
4	Functional/Performance	Graduated scale accuracy/residual volume
5	Functional/Performance	Hemolysis

CONCLUSIONS:

The results of in vitro studies demonstrate that the modified devices perform in a manner substantially equivalent to the unmodified device with respect to the relevant functional parameters. Test results of this study demonstrate that the modified devices are equivalent to unmodified device with respect to device function.
Additional testing has also demonstrated the effectiveness of production techniques to assure that the devices are sterile and non-pyrogenic.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center -- WO66-G609
Silver Spring, MD 20993-0002

June 6, 2013

Sorin Group Italia S.r.l.
Scott Light
Sorin Group USA, Inc.
14401 W 65th Way
Arvada, CO 80004

Re: K131103
Trade/Device Names: XRES Blood Collection Reservoir
XRES 120µm Blood Collection Reservoir
Regulation Number: 21 CFR 870.4400
Regulation Name: Cardiopulmonary Bypass Blood Reservoir
Regulatory Class: Class II
Product Code: DTN
Dated: May 6, 2013
Received: May 7, 2013

Dear Scott Light:

We have reviewed your Section 510(k) premarket notification of intent to market the devices referenced above and have determined the devices are substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the devices, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your devices are classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your devices in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your devices comply with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Matthew G. Hillebrenner

for Bram Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indication for Use:

510(k) Number (if known): K131103

Device Name: XRES Blood Collection Reservoir

Indication for Use: The device is an accessory to an autotransfusion device and is intended for the sterile collection and filtration of recovered blood for subsequent processing for autotransfusion

Device Name: XRES 120µm Blood Collection Reservoir

Indication for Use: The device is an accessory to an autotransfusion device and is intended for the sterile collection and filtration of recovered blood for subsequent processing for autotransfusion

Prescription Use___X____
(Part 21CFR 801 Subpart D)

Over-the- Counter Use_____
AND/OR (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Matthew G. Hillebrenner